

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1538V

UNPUBLISHED

JEAN CLAPPE-MIXELL,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 13, 2022

Special Processing Unit (SPU);
Entitlement to Compensation; Ruling
on the Record; Findings of Fact;
Onset and Site of Vaccination;
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

David John Carney, Green & Schafle LLC, Philadelphia, PA, for petitioner.

Andrew Henning, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

On October 2, 2019, Jean Clappe-Mixell filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”) caused by an influenza (“flu”) vaccine administered on October 6, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons described below, I find that Petitioner is entitled to compensation.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

On June 15, 2021, Respondent filed a Rule 4(c) Report recommending that compensation be denied. Respondent's Rule 4(c) Report (ECF No. 34). Respondent's position was based in part on arguments that the records indicate Petitioner received a flu vaccine in her *right* shoulder, and that she failed to establish onset of her injury within forty-eight hours of vaccination. *Id.* at 7. Thereafter, in a scheduling order filed on July 6, 2021, Petitioner was ordered to file a motion for a ruling on the record. ECF No. 35. The motion was to lay out Petitioner's arguments "specifically addressing Respondent's positions as set forth in the Rule 4(c) Report." *Id.*

Petitioner filed the motion on August 6, 2021. Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Mot."), ECF No. 36. Petitioner argued that she meets the table definition of a SIRVA, and also requested an award of \$95,000.00 for actual pain and suffering, \$2,160.26 for out-of-pocket expenses, and \$139.57 for out-of-pocket medical mileage. Mot. at 33.

Respondent filed his response on October 5, 2021. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 38. Respondent argued (consistent with his Rule 4(c) Report) that Petitioner failed to establish a Table claim because she alleges a left shoulder SIRVA, but the vaccination record documents the vaccine was administered in her right shoulder, and that she failed to establish onset of her injury within forty-eight hours of the vaccination. Opp. at 6-9. Respondent further notes that Petitioner's briefing on damages is premature, and thus declined to address it. Opp. at 1.

Petitioner filed a reply on October 12, 2021, addressing Respondent's arguments. Petitioner's Reply to Respondent's Response to Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Reply"), ECF No. 39. This matter is now ripe for resolution.

II. Petitioner's Medical Records

Petitioner received a flu vaccine on October 6, 2016. Ex. 2 at 1. The record of vaccination indicates the vaccine was administered in Petitioner's right arm. *Id.* Petitioner's prior medical history includes a stroke on April 3, 2016, that resulted in weakness of the left side of her body. See Ex. 5 at 3 (physical therapy record from June 20, 2016).

Petitioner saw an acupuncturist a week later, on October 13, 2016, for back pain related to her previous stroke. Ex. 6 at 1. The acupuncturist noted neck and shoulder tension, but there is no reference to shoulder pain. *Id.* at 10. Four additional visits in October and November of 2016 noted similar complaints, but these records also include no specific references to shoulder pain. *Id.* at 9-10. On December 8, 2016, however, Petitioner reported to the acupuncturist “L shoulder pain @ flu shot injection site *when* lifts/uses arms”. *Id.* at 9 (emphasis added). Petitioner again reported left shoulder pain “from injection site (flu shot)” on December 15, 2016. *Id.* at 8. None of these records suggest that the pain *began* at the time of vaccination.

Around the same period, on November 9, 2016, Petitioner had a massage therapy appointment. Ex. 13 at 3. The therapist noted that “[c]lient concerned that after a flu shot [left] side has been in excruciating pain. [Left] shoulder pain, neck pain, [lower back] pain.” *Id.* Petitioner again reported left shoulder pain at a massage therapy appointment on November 28th – and now identified it as having “appeared *right after* flu shot.” *Id.* at 4. She now reported pain levels of 8 out of 10. *Id.* at 4. Petitioner had another massage therapy session on November 30, 2016, and again reported left arm and shoulder pain. *Id.* at 5. The record notes Petitioner was “very concerned with [her left] arm area of flu shot.” *Id.* Petitioner again reported pain levels of 8 out of 10 in her left shoulder pain at a massage therapy session on December 20, 2016. *Id.* at 6.

On January 19, 2017, Petitioner saw Stacy McClain, ARNP. Ex. 3 at 5. The chief complaint was “[left] shoulder pain since flu shot in oct (done @ kmart)”. *Id.* The record also states that Petitioner “had a flu shot at K-Mart back in October and that her left shoulder has bothered her since. She reports that she is losing ROM the longer it hurts.” *Id.* at 7. An exam showed Petitioner exhibited limited range of motion and tenderness in her left shoulder, and reduced strength in her left upper arm. *Id.* at 7.

An MRI was performed on January 23, 2017. Ex. 3 at 40. The clinical history notes “2 months left shoulder pain and low ROM since flu shot....” *Id.* Petitioner was thereafter seen by Dr. Ronald Constine on February 13, 2017. Ex. 7 at 4. She stated that she had a shoulder injury related to vaccine administration and reported left shoulder pain at that time. *Id.* Petitioner was diagnosed with left adhesive capsulitis, physical therapy was recommended, and a cortisone injection was performed. *Id.* at 5, 7.

On February 22, 2017, Petitioner had an initial PT evaluation for left shoulder adhesive capsulitis “that began in October.” Ex. 5 at 22. The record from this visit also states that Petitioner received a flu vaccine in October and “since then, she has noticed increased stiffness and pain in her left shoulder.” *Id.* She reported pain levels of 0-8 out of ten, exhibited reduced range of motion and weakness. *Id.* at 23.

On March 13, 2017, Petitioner again saw Dr. Constine. Ex. 7 at 8. Dr. Constine noted that, at that time, Petitioner had improved but still had reduced range of motion. *Id.* At a follow-up appointment with Dr. Constine on July 17, 2017, her range of motion was further improved. *Id.* at 9. Dr. Constine noted during another follow-up appointment on August 28, 2017, that Petitioner's "left shoulder lacks about 10 degrees of terminal abduction forward flexion" but that she "has mild residual physical findings consistent with capsulitis." *Id.* at 12.

On September 14, 2017, Petitioner saw Jennifer Roberts, a physician's assistant, for left shoulder pain that "started after she had a flu vaccination done on 10/6/16." Ex. 8 at 8. Petitioner reported moderate pain and received a second steroid injection. *Id.* at 9. An x-ray showed no evidence of "significant glenohumeral degenerative changes." *Id.* at 11. Petitioner next had a follow-up appointment with Jennifer Roberts on October 19, 2017, and reported that she was "doing much better. She has made good progress in the last 4 weeks at physical therapy." Ex. 8 at 12.

Petitioner continued to attend physical therapy sessions for shoulder pain and reduced range of motion until November 6, 2017, for a total of 35 physical therapy sessions. Ex. 5 at 28-102. Petitioner reported that she was improving overall. See, e.g., Ex. 5 at 90 (physical therapy session from October 2, 2017, wherein Petitioner stated that "this round of therapy has improved L shoulder tremendously"). She often reported no pain at rest, but mild pain with movement. See, e.g., Ex. 5 at 94 (physical therapy record from October 5, 2017, reporting pain as 1-2 out of 10 with activity, but 0 out of 10 at rest).

The following year, on August 1, 2018, Petitioner saw orthopedic surgeon Gregory Gebauer for low back pain. Ex. 7 at 27-28. Shoulder issues were not addressed, although she was noted as having full strength in her upper extremities. After another treatment gap, Petitioner was seen again by Jennifer Roberts on March 6, 2019, for left shoulder pain. Ex. 8 at 17. At that time, she stated that she had intermittent symptoms for the past year and a half. Upon examination, she showed slight reduced range of motion, some tightness and discomfort at the end range of her rotation, but full strength. *Id.* at 18. She had another x-ray taken, which was unremarkable, and received another steroid injection.

III. Affidavit Evidence

Petitioner submitted an affidavit in support of her claim on October 4, 2019. Ex. 16. She stated that she is right handed, and thus opted to receive the vaccination in her left arm. *Id.* at 1-2. Petitioner described the onset of her shoulder pain as "immediate" at the time of the injection. *Id.* at 2. Further, she stated that over the next few weeks her shoulder

became stiff, affecting her sleep. *Id.* By early November 2016, her shoulder pain had increased. *Id.* Additionally, Petitioner explained how her injury has affected her life, and the ongoing symptoms she experiences.

IV. Parties' Arguments

Petitioner requests that I issue a ruling finding that she received a flu vaccine in her left shoulder on October 6, 2016, and that the onset of her pain was within 48 hours of that vaccination. Mot. at 32-33. She avers that she meets the requirements for a SIRVA as described in the Vaccine Injury Table, and thus is entitled to compensation. Mot. at 8-13. Respondent argues that Petitioner has failed to show she suffered a Table claim because the record indicates a right shoulder vaccination, and because she did not experience pain within 48 hours of her vaccination. Opp. at 6-9.

V. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,³ a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

³ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Petitioner Received a Flu Vaccine in her Left Shoulder.

Respondent contends that Petitioner cannot meet the Table criteria because, while she alleges a left SIRVA, the vaccine record indicates the vaccination was given in the right arm. Opp. at 6. Respondent is correct, but his argument does not take into account the totality of the evidence.

The overall medical records, coupled with Petitioner’s witness statement, establish that Petitioner consistently and repeatedly reported to treaters left shoulder pain that was caused by a flu vaccine received *in that shoulder*. *See, e.g.*, Ex. 3 at 5 (record stating that Petitioner was experiencing left shoulder pain since a flu shot); Ex. 5 at 22 (physical therapy records for left shoulder pain). Further, records from November and December of 2016 specifically establish that Petitioner was receiving care for left shoulder pain at the injection site. Ex. 6 at 9 (December 15, 2016, record reporting left shoulder pain at “flu shot injection site); Ex. 13 at 5 (November 9, 2016, record stating Petitioner was concerned with her left arm “area of flu shot”).

These records provide sufficient evidence that the vaccine was likely administered in Petitioner's left shoulder to overcome the contrary administration record (which lacks corroboration on its own). The subsequent treatment records gain strength as well given their temporal proximity to the date of vaccination.

2. Petitioner has no Prior Left Shoulder Condition or Injury

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Prior to her vaccination, Petitioner suffered a stroke that resulted in reduced *strength* in her left side. Ex. 5 at 3. However, there are no reports of significant reduced range of motion or pain in her shoulder associated with that stroke. *Id.* I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain her symptoms.

3. Onset of Petitioner's Injury was within Forty-Eight Hours of her Flu Vaccination

The medical records, coupled with Petitioner's witness statement, establish onset of her injury close-in-time to vaccination. Admittedly, this presents a closer issue – but sufficient evidence supports Petitioner's contention to find she has met her preponderant evidentiary burden.

Petitioner first sought treatment approximately four weeks after her October 6, 2016, vaccination. In the subsequent timeframe, she consistently reported to treaters that she had experienced symptoms close-in-time to vaccination. Ex. 13 at 3 (November 9, 2016, massage therapy record stating that Petitioner concerned that “after a flu shot ... has been in excruciating pain”); *id.* at 4 (November 28, 2016, record stating that pain appeared “right after flu shot”); Ex. 3 at 5 (January 19, 2017 record indicating Petitioner was being seen for “[left] shoulder pain since flu shot”).

Respondent argues that contemporaneous medical records from the earlier period of October-November 2016 fail to report shoulder pain (or that she even received a vaccination), and indicate any shoulder symptoms were actually related to her stroke earlier that year. Opp. at 7-8. Further, Respondent notes that the references to when the shoulder pain began are “vague, at best”. *Id.* 8-9.

Respondent's objections have merit, but are outweighed by other evidence. First, the records show that Petitioner noted shoulder pain “after a flu shot” in a relatively timely manner (*i.e.* approximately one month after vaccination). It is common for SIRVA

petitioners to delay seeking treatment, thinking the injury will resolve on its own, since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. Here, however, the delay was not appreciably long – and the fact that treatment was sought in a relatively short timeframe is supportive of a close-in-time onset. Such individuals also often misconstrue the nature of their injury, and may not inform treaters of all specific facts relevant to its onset until later. Here, the added detail of onset did not “wait” for months before being provided, but began to be reported in a reasonable time post-vaccination.

Second, Petitioner affirmatively and repeatedly linked her shoulder pain to the flu vaccine, beginning as early as November 9, 2016. Ex. 13 at 3. This reporting provides additional support for onset. Other subsequent medical records also corroborate the contention that Petitioner’s pain began within 48 hours of vaccination. *See, e.g.*, Ex. 13 at 4 (stating Petitioner’s pain “appeared right after flu shot”); Ex. 3 at 40 (MRI record stating “left shoulder pan and low ROM since flu shot...”); Ex. 5 at 22 (February 22, 2017, record stating Petitioner received a flu shot and “since then” experienced increased stiffness and pain in her left shoulder). Petitioner’s affidavit provides additional corroborating evidence for onset of her injury. Petitioner stated that her pain was “immediate” and increased in the weeks following her vaccination. Ex. 16 at 1-2.

Accordingly, and based upon the above, I find there is preponderant evidence that establishes the onset of Petitioner’s left shoulder pain was more likely than not within 48-hours of vaccination. The lack of mention of shoulder pain to the acupuncturist does suggest that her injury was not sufficiently severe (since an acupuncturist is the kind of treater to whom a person would reasonably be expected to report shoulder pain), but this can be factored into Petitioner’s damages – it does not appreciably undermine the preponderant likelihood of Table onset.

4. Petitioner’s Pain was Limited to her Left Shoulder

I also find that there is a preponderance of evidence that Petitioner’s pain was limited to her left shoulder. Respondent does not contest this aspect of Petitioner’s claim, and the records consistently report shoulder pain and loss of range of motion in her left shoulder. Accordingly, preponderant evidence establishes that Petitioner’s pain was limited to her left shoulder.

5. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner’s current symptoms. 42 C.F.R. §

100.3(c)(10)(iv). Respondent has not contested that Petitioner meets this criterion, and I find there is no evidence in the record to the contrary. Thus, the record contains preponderant evidence establishing that there is no other condition or abnormality which would explain the symptoms of Petitioner's left shoulder injury.

B. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on October 6, 2016, in the United States. Ex. 2 at 1; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Petition at 6; Section 11(c)(1)(E) (lack of prior civil award).

As stated above, I have found that the onset of Petitioner's left shoulder pain was within 48 hours of vaccination. See 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this requirement). This finding also satisfies the requirement that Petitioner's first symptom or manifestation of onset occur within the time frame listed on the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(B) (listing a time frame of 48 hours for a Table SIRVA following receipt of the influenza vaccine). Therefore, Petitioner has satisfied all requirements for a Table SIRVA.

The last criteria which must be satisfied by Petitioner involves the duration of her SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer the residual effects of his or her left shoulder injury for more than six months or required surgical intervention. See Section 11(c)(1)(D)(i) (statutory six-month requirement). The records demonstrate, and Respondent does not contest, that Petitioner suffered the residual effects of her shoulder injury for more than six months. See, e.g., Ex. 5 at 94 (records showing continued sequela as of at least October 5, 2017). Thus, this requirement is also met.

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

VI. Damages

Petitioner requests an award of \$95,000.00 for actual pain and suffering, \$2,160.26 for out-of-pocket medical expenses, and \$139.57 for out-of-pocket medical mileage. Mot. at 1, 13-27; Reply at 1, 15-16. Respondent argues that the scheduling order specified that only entitlement would be addressed in the ruling on the record. Opp. at 1. Petitioner's briefing on damages is therefore premature. *Id.*

Petitioner urges me to deny Respondent any opportunity to address damages because he failed to do so in his opposition. Reply at 6. However, as Respondent correctly notes, the scheduling order specified that Petitioner should address Respondent's positions as set forth in the Rule 4(c) Report with regard to entitlement. ECF No. 35. Therefore, I agree with Respondent that briefing on damages was premature (although since briefing on damages has now begun, the overall process of deciding damages can be concluded in a shorter period).

VII. Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Petitioner received a vaccination in her left shoulder and the onset of Petitioner's injury, specifically shoulder pain, was within 48 hours of her vaccine. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

Given that Petitioner has already provided his damages briefing, Respondent's brief in support of damages is due by June 13, 2022.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master